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Docket No. MTSU-1001US

U.S. Patent Application No. 09/806,925

118. The method according to claim 116, wherein the solvent for extraction is a mixture of ethanol and water in a volume ratio of 60 or less parts by volume of ethanol to 40 or more parts by volume of water.

119. The method according to claim 106, wherein the sugar cane-derived extract is administered in a form of food, which comprises the sugar cane-derived extract.

120. The method according to claim 119, wherein the food is an animal feed.--

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REMARKS

Claims 1-60 have been canceled without prejudice to resubmission. New claims 61-120 have been added. New claims 61-120 have been submitted to characterize the invention as a method rather than as a composition. Claims 61-120 are currently pending in the present application.

The withdrawal of the restriction requirement by the Examiner in the Office Action is acknowledged with appreciation. Unity of Invention is present in claims 61-120 for the same reasons as in original claims 1-60, namely that each of the claims contain the same special technical feature of a sugar cane-derived extract.

The drawings were objected to on the basis that the writing is small, cut off and illegible. According to MPEP §1893.03(f), the drawings for the national stage application provided by the International Bureau have already been checked for compliance with PCT Rule 11 and thus these drawings should be in compliance with PCT Rule 11. Accordingly, it is submitted that the drawings are in compliance with PCT Rule 11 and withdrawal of the objection to the drawings is

requested. If the Examiner considers that the drawings do not comply with PCT Rule 11, it is requested that the Examiner provide specific details as to which drawings are not in compliance and give reasons why these drawings are not in compliance in order to facilitate applicant's task of correcting the drawings, if necessary.

Claims 1-15, 19, 28, 34, 43 and 46-60 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because these claims recite "a preventative." Claims 1-15, 19, 28, 34, 43 and 46-60 have been canceled thereby obviating this rejection. None of new claims 61-120 use the term, "a preventative."

Claims 1-15, 19, 28, 34, 43 and 46-60 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because these claims recite "for infection" without stating what kind of infection is being prevented or remedied. Claims 1-15, 19, 28, 34, 43 and 46-60 have been canceled thereby obviating this rejection. New claims 61-75 recite "an infection" but all of these claims specify that the kind of infection being prevented or remedied is selected from the group consisting of bacterial infections, viral infections and fungus infections. Accordingly, favorable consideration and withdrawal of this rejection is requested.

Claims 4, 19, 34 and 49 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because the Examiner considers "utilizing differences in affinity for ion exchange" to be unclear. Claims 4, 19, 34 and 49 have been canceled without prejudice to resubmission thereby obviating this rejection. New claims 64, 79, 94 and 109 use the language "utilizing differences in affinity for an ion exchange resin packed in a column as the fixed carrier." It is considered that this language is definite since it clarifies that the differences in affinity are for the ion exchange resin. Specifically, different materials have different affinities for a particular ion exchange resin, which cause some materials to absorb onto the resin at

different rates, or under different conditions than other materials. These different absorption rates and/or conditions can be used to separate one material from another in the manner claimed. Favorable consideration and withdrawal of the rejection is requested.

Claims 13, 28, 43 and 58 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because the Examiner considered these claims unclear as to whether the water or the ethanol is the component with the lower content in the mixture. Claims 13, 28, 43 and 58 have been canceled thereby obviating this rejection. New claims 73, 88, 103 and 118 require "a mixture of ethanol and water in a volume ratio of 60 or less parts by volume of ethanol to 40 or more parts by volume of water." It is considered that this language clarifies the relative water/ethanol contents of the mixture. Favorable consideration and withdrawal of the rejection is requested.

Claim 46 and its dependents have been rejected under 35 U.S.C. §112, second paragraph, on the basis that these claims are drawn to a growth promoter. Claim 46 and its dependents have been canceled without prejudice to resubmission thereby obviating this rejection. New claims 106-120 are drafted to clearly indicate that the method of these claims is directed to promoting the growth of humans or animals. Accordingly, favorable consideration and withdrawal of the rejection is requested.

Claims 1-3, 16-18, 31-33 and 46-48 have been rejected under 35 U.S.C. §102(b) as being anticipated by JP 11189519 A (Kawai). Claims 1-3, 16-18, 31-33 and 46-48 have been canceled without prejudice to resubmission thereby obviating this rejection.

With respect to the newly-presented method claims 61-120, the specified uses for preventing or remedying an infection in humans or animals, as a vaccine adjuvant, for preventing or remedying a disease caused by an endotoxin, or for promoting growth of humans or animals

are not disclosed or suggested by Kawai, as is recognized by the examiner. Thus, new claims 61-120 are novel over Kawai for at least this reason. Favorable consideration and withdrawal of the rejection is respectfully requested.

Claims 1, 16, 31 and 46 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bueno (1992). Claims 1, 16, 31 and 46 have been canceled without prejudice to resubmission thereby obviating this rejection.

With respect to newly submitted claims 61-120, in Bueno, sugar cane is subjected to alkaline digestion, alkaline bleaching and precipitation. The cellulose obtained is then dried and pulverized. The process is "to obtain fibrous cellulose for pharmaceutical purposes." The present sugar cane-derived extract is not cellulose, but is to the contrary, other sugar cane derived substances, which are contained in an extracting liquid. Cellulose is a residue in the process of obtaining the sugar cane-derived extract, which is not present in any substantial amount in the extracting liquid in the present invention and is discarded.

The Examiner took the position that the Bueno abstract refers to obtaining "pharmaceuticals" from sugar cane. However, a careful reading of Bueno shows that Bueno refers to "pharmaceutical cellulose" and not to "pharmaceuticals" *per se*. Thus, it is clear that the materials obtained and employed in the methods of the present invention are not the "pharmaceutical cellulose" of Bueno. Accordingly, favorable consideration and withdrawal of the rejection are requested.

Claims 1, 14-16, 29-31, 44-46 and 59-60 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,374,316 (Tilby). Claims 1, 14-16, 29-31 and 44-46 have been canceled without prejudice to resubmission thereby obviating this rejection.

With regard to newly submitted claims 61-120, the invention of Tilby is to process sugar cane, and more specifically to separate the stalks into their rind and pith constituents (see col. 1, lines 6-9). Among the products which can be made from sugar cane constituents separated by the Tilby system are sugar in a variety of forms, foods and food additives, animal feeds, a variety of wood products and building materials, alcohol for a variety of purposes, paper and other pulp-containing products, and a variety of specialty products. (See col. 2, line 63 to col. 3, line 2). Tilby does not describe or suggest the present sugar cane-derived extract and, moreover, does not suggest the present uses of the sugar cane-derived extract. Accordingly, favorable consideration and withdrawal of the rejection over Tilby is requested.

Claims 1, 11-13, 16, 26-28, 31, 41-43, 46 and 56-58 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,788,812 (Agar et al.). Claims 1, 11-13, 16, 26-28, 31, 41-43, 46 and 56-58 have been canceled without prejudice to resubmission thereby obviating this rejection.

With respect to newly submitted claims 61-120, Agar et al. does not describe or suggest the claimed uses of the sugar cane-derived extract. Thus, these claims are also novel over Agar et al. Favorable consideration and withdrawal of the rejection is respectfully requested.

Claims 1-7, 9, 14, 16-22, 24, 29, 31-37, 39, 44, 46-52, 54 and 59 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,482,631 (Saska et al.). Claims 1-7, 9, 14, 16-22, 24, 29, 31-37, 39, 44, 46-52, 54 and 59 have been canceled without prejudice to resubmission thereby obviating this rejection.

With respect to newly submitted claims 61-120, Saska discloses a method for separating an inositol from an aqueous phase comprising inositol and other sugars. The separation is done by

adsorption of inositol on an ion exchange resin. (See claim 1). The parts of column 1 of *Saska* cited by the examiner relate to the prior art and mention a method for obtaining additional sucrose from molasses. In the prior art method, a cation exchange resin is used to separate molasses into raffinate which contains no sugar, an extract which mainly contains sucrose, and an invert syrup which contains monosaccharides. It has been found that the invert syrup may be used as a feedstock for industrial inositol separation since inositol does not separate well on the cation exchange resin; and the invert syrup is a colored product, which is preferably demineralized and decolorized in ion exchange and activated carbon columns. These portions of the background section of *Saska* do not describe or suggest the present invention as claimed in new claims 61-120.

The disclosure at column 4, lines 8-11 and in Example 1 of *Saska*, cited by the examiner relates to embodiments of the method of the claim for separation of inositol as mentioned above. The description in col. 1, lines 10-15 of *Saska*, relates to the use of myo-inositol. These portions of the *Saska* disclosure do not describe or suggest the present invention as claimed in new claims 61-120, either. In addition, *Saska* does not describe or suggest the present uses of the sugar cane-derived extract. Favorable consideration and withdrawal of the rejection are respectfully requested.

Claims 1-2, 4, 8, 10, 16-17, 19, 23, 25, 31-32, 34, 38, 40, 46-47, 49, 53 and 55 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,482,631 (*Saska et al.*) in view of JP 69023346 B (*Kaken Chem Co.*). Claims 1-2, 4, 8, 10, 16-17, 19, 23, 25, 31-32, 34, 38, 40, 46-47, 49, 53 and 55 have been canceled without prejudice to resubmission thereby obviating this rejection.

As mentioned above, Saska discloses a method for separating inositol from an aqueous phase comprising inositol and other sugars. The separation is done by adsorption of inositol on an ion exchange resin. (See claim 1 of Saska). Meanwhile, Kaken Chem Co. discloses a method of obtaining a substance having anti-tumor activity. The method comprises extracting a plant including sugar cane with a cold alkaline material. First, there is no reason to combine the method of Saska with the method of Kaken. The mere fact that a process is well known does not provide a skilled person with a motivation to combine that process with any other process as suggested by the examiner. Instead, the skilled person must have some reason for combining the two processes.

Moreover, in Kaken Chem Co., the anti-tumor activity is confirmed in solid tumor, sarcoma 180, in a mouse. This does not relate directly to infections by bacteria, virus or fungi; to a vaccine adjuvant; to a disease caused by an endotoxin; or to the promotion of the growth of humans or animals. Therefore, the present invention, as claimed in newly submitted claims 61-120, is not obvious from a combination of Saska and Kaken Chem Co. Favorable consideration and withdrawal of the rejection are requested.

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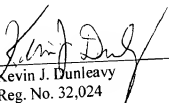
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Favorable consideration and issuance of a Notice of Allowance are solicited. Should the Examiner have any questions she is encouraged to call the Applicant's representative listed below.

Respectfully submitted,

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